commodity is 100% of a daily diet. Thus, in making a safety determination for these tolerance exemptions, Valent BioSciences Corporation took into account this very conservative exposure assessment.

The last application precedes harvest by approximately 2.5 months in apples, therefore the potential for dietary exposure is considered negligible by Valent BioSciences Corporation. Application precedes harvest by approximately 2 months in pistachios. Also pistachios have their hulls, which cover the shell, removed at harvest, therefore the potential for dietary exposure is considered negligible by Valent BioSciences Corporation. Residues are below the LOQ (LOQ = 0.05 ppm) in pistachio.

ii. *Drinking water*. The proposed uses on apples and pistachios are not expected to add potential exposure to drinking water. Soil leaching studies have suggested that 6-BA is relatively immobile, absorbing to sediment. Residues reaching surface waters from field runoff should quickly absorb to sediment particles and be partitioned from the water column. 6-Benzyladenine also has low solubility in water, 0.061 mg/mL, and detections in ground water are not expected. Valent BioSciences Corporation concludes that together these data indicate that residues are not expected in drinking water.

2. *Non-dietary exposure*. The proposed uses involve application of 6-BA to crops grown in an agricultural environment. The only non-dietary exposure expected is that to applicators. However, the protective measures prescribed by the product's label are expected to be adequate to minimize exposure and protect applicators of the chemical.

E. Cumulative Exposure

No cumulative adverse effects are expected from long-term exposure to this chemical. There is no reliable information to indicate that toxic effects produced by 6-BA would be cumulative with those of any other pesticide chemical.

F. Safety Determination

1. *U.S. population*. Chronic dietary exposure estimates were conducted for the overall U.S. population and 25 population subgroups, including infants and children. These estimated daily intakes were compared against a chronic population adjusted dose (PAD) based on a NOAEL of 50 mg/kg bwt/day from a developmental study in rats. To account for intraspecies and interspecies variation and the use of an acute toxicological endpoint for a chronic assessment, an uncertainty factor (UF) of 1,000 was applied to the acute NOAEL. This resulted in a chronic PAD of 0.05 mg/kg bwt/day. Daily exposure for the overall U.S. population was estimated to be 0.000014 mg/kg bwt/day, representing less than 0.1% of the estimated chronic PAD.

2. *Infants and children*. Estimated daily exposures, assuming that 100% of the apple and pistachio commodities in the United States are treated with 6-BA, for the most highly exposed population subgroup, non-nursing infants, was estimated to be 0.000085 mg/kg bwt/day, or 0.2% of the estimated chronic PAD.

G. Effects on the Immune and Endocrine Systems

6-Benzyladenine is a naturally occurring cytokinin which has plant growth regulator properties. There is no indication that this plant growth regulator belongs to a class of chemicals known or suspected of having adverse effects on the immune and endocrine systems. It can be concluded that based upon the existing toxicology there would be no adverse effects on the immune or endocrine systems from the use of 6-BA. Last, there is no evidence that 6-BA bioaccumulates in the environment.

H. Existing Tolerances

The plant growth regulator 6-BA is exempt from the requirement of a tolerance when used as a fruit-thinning agent at an application rate not to exceed 30 grams of active ingredient per acre in or on apples.

6-Benzyladenine is temporarily exempt from the requirement of a tolerance in or on apples at ≦182 grams of active ingredient per acre per season, and in or on pistachio at ≦60 grams of active ingredient per acre per season when used in accordance with the Experimental Use Permit 73049–EUP–2. The exemption from a tolerance will expire on January 31, 2005.

I. International Tolerances

There are no codex, Canadian, or Mexican maximum residue limits for use of 6-BA on apple or pistachio.

[FR Doc. 03–19280 Filed 7–29–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0256; FRL–7319–7]

Indian Meal Moth Granulosis Virus; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2003–0256, must be received on or before August 29, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Leonard Cole, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5412; e-mail address: *cole.leonard@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0256. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search, '' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2003–0256. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to *opp-docket@epa.gov*, Attention: Docket ID Number OPP–2003–0256. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2003–0256.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP–2003–0256. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 21, 2003.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

AgriVir, LLC

PP 3F6736

EPA received a pesticide petition (PP 3F6736) from AgriVir, LLC, 1901 L St., NW., Suite 250, Washington, DC 20036, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR 180.1218 to expand the tolerance exemption from the existing exemption for use on dried fruits and nuts to use on all agricultural commodities and relevant processed fractions. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not completed a review of the sufficiency of the submitted data at this time. The summary represents the views of AgriVir, LLC. EPA is still in the process of evaluating the petition. EPA has made minor edits to the summary for the purpose of clarity.

A. Residue Chemistry

Residue chemistry, *per se*, is not required in support of the proposed tolerance exemption. This is because EPA has waived this requirement for microbial pet control agents which do not trigger Tier II toxicology concerns. Indian Meal Moth Granulosis Virus (IMMGV) does not trigger Tier II toxicology concerns. A brief summary of the identity of the microbial pest control agent IMMGV follows for information purposes

EPA has previously registered AgriVir's microbial pest control product FruitGuard-V/NutGuard-V (these are alternate names for the same product), EPA Reg. No. 73176–1. This is a biological insecticide intended to control Indian meal moth, a serious pest of various stored commodities.

The Indian meal moth, is a serious cosmopolitan pest of many stored agricultural commodities and processed fractions. Infestation can occur at any time from harvest to eventual consumption of the commodity. Indian meal moth, is estimated to be responsible, for example, for approximately 90% of the damage done to dried fruits and nuts in storage. In facilities where susceptible commodities are handled, fragments and other debris from the commodities gets into cracks, crevices, and other places and Indian meal moth, propagates on this material. This establishes a general infestation and reservoir for the Indian meal moth in such facilities.

Control of Indian meal moth by FruitGuard-V/NutGuard-V is by means of a naturally occurring microbial pest control agent (MPCA) which is contained in the product.

The MPCA used in NutGuard-V/FruitGuard-V is a granulosis virus which infects the larvae of the Indian meal moth. This virus is designated IMMGV in the balance of this summary. The MPCA contained in NutGuard-V/FruitGuard-V is a naturally occurring isolate of the IMMGV. It has not been genetically modified.

IMMGV has no hosts other than larvae of the Indian meal moth and acts by making the Indian meal moth larvae sick, rather than by a toxic mechanism (i.e., IMMGV does not produce any specific toxin which kills the larvae).

Indian meal moth larvae succumb to granulosis disease due to serious damage to one of their major organs for storage of nutrients.

The above-cited products are equivalent to a technical grade of IMMGV. They are prepared without isolation of IMMGV and, as such, the MPCA which is the subject of the present petition consists, therefore, of IMMGV occlusion bodies (viral particles) and Indian meal moth larval parts mixed into a production larval diet containing wheat bran, brewer's yeast, vitamins, methyl paraben, and sorbic acid.

B. Toxicological Profile

The mode of action for IMMGV in its host, the larval stage of *P. interpunctella*, is pathogenic in nature. IMMGV produces granulosis disease in the larvae of *P. interpunctella*. ''Granulosis'' disease is so named because cells in infected tissue sections, when observed under light microscopy, are full of minute, refractile bodies termed ''granules.'' The initial signs of granulosis disease occur several days after larval ingestion of the viral occlusion bodies and consist of sluggishness and loss of appetite. These initial signs are followed by a change in the appearance of the larvae. They are normally light brown and semilucent but when infected become opaque and white. This change is the result of the massive accumulation of viral occlusion bodies in the fat body of the infected larva. The fat body is the site of intermediary metabolism in these larvae and it is in the fat body that fat, protein, and glycogen are primarily stored. The pathogenicity of IMMGV to the larva results from the mode of viral release from cells of the fat body. As discussed above, this occurs by rupture of the cells of the fat body, thereby leading to degeneration and necrosis of the fat body and, ultimately, death of the infected larva.

The above-cited mode of action is distinct from a toxicity based mode of action. That is, unlike some microbial pest control agents which produce endo- or exo-toxins which act to kill the target pest, IMMGV produces no toxins as part of its mode of action.

1. *Hazard potential to mammals*. IMMGV poses no hazard potential to mammals via ingestion, dermal contact, or inhalation. There is no baculovirus (the type of virus which IMMGV is) known to infect or replicate in any vertebrate host. Among invertebrates, IMMGV itself has no known host other than larvae of *P. interpunctella* and has been shown not to cross-infect lepidopteran or other insects other than *P. interpunctella*.

A number of studies on the toxicity of baculoviruses, inclusive of granulosis viruses, to animals have shown that these agents are non-toxic by the oral, dermal, inhalation, and injection routes of exposure and that no effects on overall health, gross or micro pathology, hematology, clinical chemistry, and antibody stimulation occur in test animals. These studies have been published in the open literature and were submitted as part of AgriVir, LLC's petition.

Cell culture studies (submitted by AgriVir as part of its submission) have shown that IMMGV which is actively infective and pathogenic to IMM larva does not produce cytotoxicity nor does it replicate in or produce pathogenicity in the following mammalian cell lines:

WI-38 (ATTC CCL 75: human lung (embryonic))

WS1 (ATTC CRL 1502: human endothelium (embryonic skin))

CV-1 (ATTC CCL 70: African green monkey, renal)

These cell culture studies further support the already established fact that IMMGV poses no hazard to mammals.

Due to the physical properties of the final product and of the bran carrier, the technical MPCA does have a mild to moderate, reversible eye irritation potential.

2. *Hazard potential to the environment*. The only potential environmental effect of IMMGV is on the population of Indian meal moths. This is because, as discussed above, IMMGV has no hosts other than larvae of the Indian meal moth and acts by a pathogenicity mechanism rather than a toxicity mechanism (i.e., IMMGV does produce any specific toxin). Since IMMGV is a naturally occurring virus which has naturally infected Indian meal moth larvae for at least decades and probably longer, its use on Indian meal moth larvae which may infest dried fruits and nuts and other stored commodities cannot reasonably be expected to endanger the Indian meal moth population as a whole.

Therefore, there are no reasonably anticipated or likely environmental effects of use of IMMGV for protection of agricultural commodities from Indian meal moth damage.

3. *Hazard potential to non-target species*. There is no hazard potential to non-target species. As above-noted, there is no baculovirus known to infect or replicate in any vertebrate host. Among invertebrates, IMMGV itself has no known host other than larvae of *P. interpunctella* and has been shown not to cross-infect lepidopteran or other insects other than *P. interpunctella*.

C. Aggregate Exposure

1. *Dietary exposure*–i. *Food*. The levels of residues in treated commodities will be very low. The application rates for IMMGV are from 1 to 5 ounces of formulated (i.e., technical) MPCA per ton of commodity to be treated. Therefore, dietary exposure is insignificant.

ii. *Drinking water*. The proposed use patterns for IMMGV are for indoor food and non-food uses. Therefore, there is no potential for drinking water exposure associated with the approval of this petition.

2. *Non-dietary exposure*. IMMGV only has any pest control utility in the treatment of various commodities for control of Indian meal moth. Therefore, the only potential for non-dietary exposure is to applicators and to mixer/loaders who will use product containing IMMGV. These non-dietary exposures are not covered within FQPA and they are expected to be low. Information already in EPA's data bases which had been cited by AgriVir, LLC indicates that workers involved with baculovirus production and use do not experience adverse effects as a result of these exposures.

D. Cumulative Effects

Due to its mechanism of action and extremely limited host specificity, it can be reliably stated that IMMGV does not share a common mechanism of action with any other conventional, biochemical, or microbial pesticide.

E. Endocrine Effects

There is no reliable information to indicate that IMMGV has a potential to produce endocrine effects. The available studies suggest that IMMGV is essentially biologically inactive in any organism other than its natural host, the larva of the Indian meal moth.

F. Safety Determination

1. *U.S. population*. Since the available information reliably supports that IMMGV will not produce adverse effects in humans of any age as a result of exposure by ingestion, dermal contact, or inhalation, AgriVir, LLC concludes that there is a reasonable certainty that no harm to the general adult population will result from dietary exposure to residues which could occur as a result of approval of this petition.

2. *Infants and children*. Since the available information reliably supports that IMMGV will not produce adverse effects in humans of any age as a result of exposure by ingestion, dermal

contact, or inhalation, AgriVir, LLC concludes that there is a reasonable certainty that no harm to infants and children will result from dietary exposure to residues which could occur as a result of approval of this petition.

3. *Sensitive individuals.* Since the available information reliably supports that IMMGV will not produce adverse effects in humans of any age as a result of exposure by ingestion, dermal contact, or inhalation, and indeed that IMMGV appears to be biologically inactive in other than its natural host, AgriVir, LLC concludes that there is a reasonable certainty that no harm to sensitive persons will result from dietary exposure to residues which could occur as a result of approval of this petition.

G. International Tolerances

There are no Codex maximum residue levels established for residues of IMMGV. IMMGV containing products are presently not registered for pest control outside of the U.S.

[FR Doc. 03–19354 Filed 7–29–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7537–7]

Framework for Application of the Toxicity Equivalence Methodology for Polychlorinated Dioxins, Furans, and Biphenyls in Ecological Risk Assessment (External Review Draft); Notice of Availability

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability and opportunity for public comment.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is announcing a 60-day public comment period for the draft document titled Framework for Application of the Toxicity Equivalence Methodology for Polychlorinated Dioxins, Furans, and Biphenyls in Ecological Risk Assessment. The document is intended to describe a methodology for assessing ecological risks associated with complex mixtures of dioxins, furans, and dioxin-like PCBs in the environment. EPA will consider the public comments in revising the document.

DATES: Comments must be received by September 29, 2003.

ADDRESSES: The draft is available via the Internet at *http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=55669.* Comments may be submitted electronically, by mail, or in person, as described in the instructions under Supplementary Information. Comments may be viewed at EPA Dockets at *http://www.epa.gov/edocket* (under Docket ID No. ORD–2003–0002).

FOR FURTHER INFORMATION CONTACT: Marilyn Brower, U.S. EPA, ORD National Center for Environmental Assessment, Risk Assessment Forum Staff (8601D), 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone: 202–564–3363; fax: 202–565–0062; e-mail: *brower.marilyn@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Submission of Comments

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification number (ORD–2003–0002) in the subject line on the first page of your comment. Please note that all comments received in response to this notice will be placed in a public record. For that reason, comments should not contain personal information (such as medical data or home address), Confidential Business Information, or information protected by copyright.

A. Electronically to EPA Dockets

Your use of EPA's electronic public docket (EPA Dockets) to submit comments is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket* and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in Docket ID No. ORD–2003–0002. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it. EPA recommends that you include your name and contact information in the body of your comment to ensure that you can be identified as the submitter of the comment and to allow EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment.

B. By Mail

Comments may be sent to: Office of Environmental Information Docket, Environmental Protection Agency, Mailcode: 28220T, 1200 Pennsylvania Ave. NW, Washington, DC 20460, Attention Docket ID No. ORD–2003–0002.

C. By Hand Delivery or Courier

Deliver your comments to: Office of Environmental Information Docket, EPA West, Room B102, 1301 Constitution Ave. NW, Washington, DC, Attention Docket ID No. ORD–2003–0002. Such deliveries are only accepted during the Docket's normal hours of operation from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the docket is 202–566–1752.

II. Background

Polychlorinated dioxins (PCDDs), furans (PCDFs), and biphenyls (PCBs) commonly occur as complex mixtures in the environment. For more than a decade, EPA and other organizations have estimated the combined risks that such mixtures pose to human health using a method known as the toxicity equivalence methodology. The methodology is based on findings that certain PCDDs, PCDFs, and PCBs share a common mechanism of action for their effects but differ in potency. The methodology uses potency factors (such as Toxicity Equivalence Factors, or TEFs) assigned to each chemical in the mixture as a way of integrating the risks from the entire mixture. Application in ecological risk assessments has proceeded more slowly than in human health risk assessment, in part because of the variety of species from different taxonomic classes (*e.g.*, fish, birds, and mammals) to be considered.

As both data and experience with the methodology have accumulated, however, experts have concluded that the toxicity equivalence methodology can strengthen assessments of ecological risks. At a World Health Organization consultation in 1997, international consensus TEFs for PCDDs, PCDFs, and PCBs were reviewed and the toxicity equivalence methodology expanded to include class-specific TEFs for mammals, birds and fish. In 1998, EPA and the U.S. Department of Interior sponsored a workshop that recommended the development of further guidance on application of the toxicity equivalence methodology. This draft framework has been developed in direct response to that workshop recommendation by a technical panel under EPA's Risk Assessment Forum.

Organized in accordance with EPA's *Guidelines for Ecological Risk Assessment* (63 FR 26846), this framework is intended to assist EPA scientists in using the methodology, as well as to inform EPA decision makers, other agencies, and the public about this methodology. It provides ecological risk assessors with an understanding of the uncertainties associated with the application of the methodology in general and with situation-specific decisions made in applying the